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(H)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/949,758	10/14/97	GULDENBERG	D 016733/0808

HM12/1007

EXAMINER

MERTZ, F

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ART UNIT	PAPER NUMBER
1646	

DATE MAILED:

10/07/99 JS

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.	08949,758	Applicant(s)	Goldenberg
Examiner		Group Art Unit	
	Prena Meag	1646	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 8/18/99.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1, 3-22 are pending in the application.

Of the above claim(s) 16-19, 22 are withdrawn from consideration.

Claim(s) 8-15, 20-21 are allowed able.

Claim(s) 1, 3-7 are rejected.

Claim(s) are objected to.

Claim(s) are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

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## DETAILED ACTION

1. Applicants Appeal Brief filed on 8/18/99 in Paper No. 13 is acknowledged.
2. The finality of the rejection of the Office action is withdrawn in view of the prior art references by Nicolotti et al (U.S. Patent No. 4,837,003) and a 35 U.S.C. § 112, second paragraph rejection. The delay in citation of this art is regretted. Rejections based on this prior art follow.
3. The following previous rejections and objections are withdrawn:
  - (I) the rejection of claims 8-15 and 20-21 under 35 U.S.C. § 112, first paragraph.

### *Claim rejections-35 U.S.C. 112, second paragraph*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "said toxin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 5 is rejected insofar as it depends on claim 4 for this limitation.

### *Claim rejections-35 U.S.C. 102*

5. Claims 1, 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallinckrodt Medical, Inc. (WO 94/07535).

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (Paper No. 6, 9/28/98) and as set forth at pages 3-4 (Paper No. 9, 2/18/99).

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Applicants argue that the disclosure of Mallinckrodt Medical, Inc. Does not encompass conjugates with a therapeutic nuclide. However, contrary to Applicants arguments, the invention being claimed is the product i.e. cytokine conjugated to a radionuclide, and the word “therapeutic” is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a product. See M.P.E.P. 2111.02. (In *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)).

***Claim rejections-35 U.S.C. 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6a. Claims 1, 3, 6-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Nicolotti (U.S. Patent No. 4,837,003).

Nicolotti teaches an antibody conjugate complexed with a radionuclide metal ion which is useful in therapeutic or in vivo diagnostic techniques, examples of such radionuclide metal ions being gamma-emitting radionuclides useful in diagnosis or beta-emitting nuclides useful in therapeutic applications (see column 7, lines 18; column 2, lines 25-28). Nicolotti also teaches the antibody conjugate in a pharmaceutically acceptable carrier (see column 12, lines 20-25), but does not teach a cell-specific cytokine, IL-15 conjugated to a radionuclide.

To have conjugated a radionuclide to IL-15 cytokine to facilitate the use of the cytokine for in vivo diagnostic and therapeutic applications would have been *prima facie* obvious to an artisan in light of the Nicolotti patent because antigen-antibody complexes are analogous to ligand-cytokine complexes..

### ***Conclusion***

Claims 8-15 and 20-21 are allowable over the prior art of record.

### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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*Prema Mertz*

Prema Mertz Ph. D.

Primary Examiner

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September 22, 1999